

Reliability & validity of the Malayalam Functional Assessment of Cancer Therapy for Head & Neck Cancer

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Received October 7, 2003

Background & objectives: The need for quality over quantity in cancer survival is increasingly being recognised in the developing countries, and the efforts to monitor quality of life (QOL) are increasing. However, the non-availability of a valid and reliable tool in the local language is a common problem. Cross-culturally sensitive tools enable the researchers to compare different patient populations and identify cultural differences and variations. The present study was carried out to translate, validate and test for reliability a reliable QOL tool for the head and neck cancer patient population in a tertiary care hospital in south India.

Methods: The functional assessment of cancer therapy for head and neck cancer (FACT-H&N) was translated into the local language (Malayalam) and tested for reliability in 140 patients of head and neck cancer.

Results: The translated tool showed substantial psychometric sensitivity. The Cronbach's α for the total FACT-H&N was 0.94. The α scores for the five subscales ranged from 0.81-0.92. Significant correlations were observed amongst the total QOL and subscale scores and patient's demographic, disease and treatment variables.

Interpretation & conclusion: The Malayalam translation of the FACT-H&N questionnaire was developed, tested and validated. It was found to satisfactorily measure QOL in head and neck cancer patients.

Key words Cronbach's α - head and neck cancer - psychometry - psycho-oncology - quality of life - reliability - validity

Diagnosis of head and neck cancer (HNC) has a negative effect on the patient's social, recreational, and sexual functioning¹. HNC patients irrespective of the tumour sub-site, have been found to have numerous problems at diagnosis and significant post-treatment morbidity compared to patients with other cancers¹⁻³. Among these, physiological derangements like speech problems, dry mouth and throat, swallowing difficulties, loss of taste, and pain are of paramount importance^{1,2}. Impaired psychosocial functioning and psychological distress are also reported with worry, anxiety, mood disorder, fatigue, and depression as the main problems^{2,4}. Of all sub-sites, patients with hypopharyngeal cancer are reported to have the worst health related QOL

(HRQOL)³. Gender and age differences are evident with females showing poorer emotional functioning compared to males, and older patients showing better emotional and social functioning than younger patients³.

QOL research in HNC patients was considered in its infancy in 1996⁴. Speech and eating have been identified as predictors of QOL in HNC^{5,6} and stage of the disease appears to have the strongest relationship with HRQOL³, even though site and stage specific studies are very few⁷.

Very few studies on QOL in the Indian context exist⁷⁻¹⁵. One of the reasons is the non-availability of

valid local language tools. Translating well-documented and established questionnaires has the advantages in terms of time saved on tool development. It also provides a scope for cross-cultural validity studies, and identifying cross-cultural QOL differences. The Functional Assessment of Chronic Illness Therapy (FACIT) Measurement system's QOL tools for cancer, the Functional Assessment of Cancer Therapy (FACT), have shown substantial scope as a cross-cultural instrument in the Indian setting⁷. Despite the fact that the disease specific FACT tools contain the core General tool (FACT-G) as the generic QOL measure, the inclusion of the "Additional Concerns" subscale makes it a population specific tool that requires reliability studies in specific populations. The FACT-H&N (Head and Neck) is a 38 item questionnaire divided into five domains (4 non-specific and 1 specific). The present study was undertaken to translate, validate and test for reliability a QOL tool for the head and neck cancer patient population in a tertiary care hospital in south India.

Material & Methods

A prospective cohort study from November 2001 to May 2002 was carried out in the Regional Cancer Centre, Thiruvananthapuram, Kerala among 140 HNC patients who were undergoing or underwent curative treatment. The Malayalam version of the Functional Assessment of Cancer Therapy - Head and Neck, Version 4 (FACT-H&N) was used. The translation process was an iterative forward-backward-forward translation process in accordance with the methodology stipulated by the Center on Outcomes, Research, and Education (CORE), USA¹⁶. The study was approved by the Institution

Review Board (IRB), and the Institution Ethics Committee (IEC). Written informed consent was obtained from all the participants.

The test was administered and scored in accordance with the instructions in the manual for the version 4 of the FACIT measurement system¹⁶. Demographic variables were recorded at the time of interview while the disease and treatment variables were extracted from the case records. Statistical analyses were carried out by using product moment correlation. Reliability was estimated using Cronbach's α .

Results

Of the 140 respondents, 4 answered fewer than 80 per cent of the items and were excluded from further analysis. The final sample comprised 136 patients. The mean age was 55.3 (range 23-87 yr); average age among the male and female was 57.1 and 49.1 respectively. More than 75 per cent were male, and 44 per cent were from the low income category. Around 85 per cent were married. Over 40 per cent were Christian or Muslim, and nearly 45 per cent had four or more children. Nearly 30 per cent of the sample had received college or professional education, and about 35 per cent were employed having a steady income. Forty per cent had a stage III disease, 25 per cent had stage II disease, 20 per cent had stage I disease and nearly 15 per cent had a stage IV disease. At the time of the interview, more than 60 per cent had completed active treatment while 4 per cent had discontinued their required treatment.

The total score of the individual respondent ranged from 41.5 to 136 with the mean score of 99.3 (Table I).

Table I. Mean, ranges, standard deviation (SD), and Cronbach's α of the total scores and subscales scores of the Malayalam FACT H &N

Domain (No. of items)	Mean	Range	SD	Cronbach's α
Physical well-being (7)	21.6	3.0-28.0	5.4	0.84
Social well-being (7)	23.2	4.7-28.0	4.7	0.86
Emotional well-being (6)	17.6	1.0-24.0	4.9	0.86
Functional well-being (7)	18.4	3.0-28.0	6.8	0.92
FACT-G total (27)	80.9	33.5-108.0	18.8	0.94
Additional concerns-H&N (11)	18.4	4.0-29.7	6.5	0.81
FACT H&N Total (38)	99.3	41.5-136.0	24.8	0.94

FACT H&N, Functional assessment of cancer therapy-head and neck

Table II. Correlation matrix and significance of FACT H&N total scores and subscale scores with various parameters

	FACT H&N Total	Physical well-being	Social well-being	Emotional well-being	Functional well-being	Additional concerns -H&N
Gender	-0.0895	-0.1019	0.0085	-0.1778*	-0.0714	-0.0531
Income category	0.1622	0.0958	0.1255	0.0986	0.1876*	0.1764*
Education	0.2457**	0.2311**	0.1369	0.1779*	0.2424**	0.2569**
Days between diagnosis and treatment	-0.1525	-0.2077*	0.0130	-0.1716*	-0.1494	-0.1316
Time between end of active treatment and interview	0.3102**	0.2003	0.2491*	0.3313**	0.2808**	0.2937**
Pre-treatment symptom duration	-0.0517	0.0459	-0.0026	-0.1961*	-0.0620	-0.0230
Node involvement	-0.1965*	-0.1986*	-0.0965	-0.1586	-0.1854*	-0.2028*
Metastatic status	-0.1023	0.0025	-0.0986	-0.1526	-0.1081	-0.0936
Composite staging	-0.1733*	-0.1737*	-0.0901	-0.1885*	-0.1586	-0.1429
Treatment status at interview	-0.3017**	-0.2622**	-0.2859**	-0.2906**	-0.2541**	-0.2402**

*P**<0.05; **<0.01

The Cronbach's α for the subscales ranged from 0.81 to 0.92, while the α for the total FACT H&N was 0.94 (Table I).

The FACT H&N scores showed significantly positive correlations with patient education ($r=0.2457$; $P<0.01$) and time between end of active treatment and the interview session ($r=0.3102$; $P<0.01$). There was a significant negative correlation with nodal involvement ($r=-0.1965$; $P<0.05$), composite staging ($r=-0.1733$; $P<0.05$), and treatment status at the time of the interview ($r=-0.3017$; $P<0.01$). The emotional well-being showed a significant positive correlation with patient education ($r=0.1779$; $P<0.05$), and time between end of treatment and the interview session ($r=0.3313$; $P<0.01$). Significantly negative correlations were observed with gender ($r=-0.1778$; $P<0.05$), time between diagnosis and actual treatment ($r=-0.1716$; $P<0.05$), pre-treatment symptom duration ($r=-0.1961$; $P<0.05$), composite stage ($r=-0.1885$; $P<0.05$), and treatment status at the time of the interview ($r=-0.2906$; $P<0.001$) (Table II).

Discussion

The advantage of translating validated tools into the local language instead of developing a new one, is primarily the amount of time that is needed to establish the reliability for the translated tool. As the source tool is valid, its characteristics (face, content, construct, and factorial validity) are passed on to the translated version as the items are similar by content, implication, and structure.

The Cronbach's α of the present study indicated a very high internal consistency for the subscales as well as the translated tool as a whole. No internal consistency results have yet been documented for the English language source tool. However, as the previous versions are validated in the HNC population, and the present results showing high reliability quotient are suited to psychometric requirements, we can assume that the Malayalam version of the FACT H&N version 4 could be considered a reliable QOL tool for the HNC patients.

The present study substantiated the effects on gender differences on QOL³ in HNC patients with women

showing poorer emotional well-being. Advanced disease and intensive multi-modality treatment aggravates problems like speech disturbances, eating problems, and disfigurement. These factors accentuate psychological and social problems, such as depression, social avoidance (especially in post-surgery patients), and negative health behaviours^{4,17-20}.

Higher education status of the patient, longer time after active treatment, and completion of planned/scheduled treatment were found to influence QOL in the present study. Patients who had completed active treatment more than a year ago showed better social, emotional, functional, and disease specific well-being, and the overall QOL than those who had completed active treatment within the last 12 months. This probably reflects better coping and adjustments among disease free patients. Rehabilitation interventions could be beneficial to shorten the gap between end of active treatment and returning to a normal lifestyle.

In conclusion, the Malayalam translation of the English FACT H&N (Version-4) was developed and its sensitivity was found satisfactory. This also substantiated the cross-cultural utility of the FACT H&N questionnaires. Further long-term follow-up studies are underway to identify the QOL determinants in the Indian HNC patient population and their change over time. Results of these studies will assist in developing psychological and rehabilitation intervention programmes to meet the specific requirements of patients.

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